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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/724,816

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Thomas L. Clubb

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EXAMINER

MOULTON, ELIZABETH ROSE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/724,816	<b>Applicant(s)</b> CLUBB, THOMAS L.	
	<b>Examiner</b> ELIZABETH R. MOULTON	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-36,38-48 and 50-75 is/are pending in the application.
- 4a) Of the above claim(s) 7-11,30-32,34,39-41,44,54-58,66-68,70 and 73-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,12-29,33,35,37,38,42,43,45-48,50-53,59-65,69,71 and 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 7-11, 30-32,34, 39-41,44,54-58,66-68,70 and 73-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3 August 2006.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-6, 12-29, 33, 35-36, 38, 42, 43, 45-48, 50-53, 59-65, 69, 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson (US 4,979,951) in view of Barbut (US 5,662,671)  
Simpson teaches a catheter (Fig 3) having:

A first elongate tubular body (108) having a proximal portion (46, Fig 1A), a distal portion (at 101b, just before notch 102), and lumen extending between the proximal and distal end (Fig 4);

A second elongate tubular body (101a) having a proximal end (at 128, just after notch 102) and a distal end (see Fig 3 where guide wire 113 extends from the distal end) and a lumen (guide wire lumen 152 extending as shown in Fig 7);

An elongate member (101, only section with notch 102) joining the first and second tubular bodies;

Further comprising a third elongate member (106) having a proximal portion (connected at 116) and a distal portion (cutting edge 157, Fig 7) and a lumen;

At least the proximal portion of the third elongate body being disposed within the lumen of the first body (Fig 2C) and being slidable so that the distal portion of the third body is within the second body (Fig 2D);

Simpson shows the proximal end of the third body is not maintained within the lumen of the first body (Fig 2D- the proximal end of the third body is outside of the first body).

Barbut teaches an artherectomy catheter with a slideable third body (Fig 13A-C 262) where the third body is wider than the space between the first (50) and second (260) bodies, such that in a first position (Fig 13A or B) the third body is within the first body and in a second position (Fig 13C) the distal end of the third body is within the lumen of the second body and the proximal end is within the lumen of the first body.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the full-length cutting of Barbut with the catheter of Simpson in order to prevent any debris from entering the cutout 102 of Simpson. Debris within the cutout 102 behind the cutting head 106 would prevent the cutting head from being withdrawn and cause the catheter to malfunction, potentially releasing dangerous emboli into the blood stream.

As to claim 2, 38, see Fig 3; claims 4,5 Fig 5; claim 6, Fig 3; claim 12, Fig 5; Claim 13,14 Fig 3; claim 15, 16, 17, shaft 107; claim 29, balloon 127; claim 33, Fig 2C; claim

35, plastics are used at Col 2 line 48; claims 45-48, 50-53, 59-65, 69, 71 and 72, see Fig 2A-2E. Simpson is silent on the specific dimensions of the catheter. Shanley's catheter is sized and shaped to be used in the human vasculature, and therefore must fall within certain anatomical limitations. It would have been well within the skill of one of ordinary skill in the art at the time the invention was made to use the dimensions claimed by the applicant as a matter of optimization to allow the catheter to be used within the human vasculature.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-75 have been considered but are moot in view of the new grounds of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MOULTON whose telephone number is (571)272-9970. The examiner can normally be reached on 7:00-3:30 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767